Catalog Number PH3000

OLYMPUS PK™ TP SYSTEM

Microhemagglutination Test for Detection
of *Treponema pallidum* Antibodies
using the Olympus PK™ Instrument

I. INTENDED USE

OLYMPUS PK TP SYSTEM is intended for the qualitative screening of blood donors for the detection of *Treponema pallidum* IgG and IgM antibodies in human serum or EDTA plasma using the OLYMPUS PK7200, Automated Microplate System.

This assay is not intended for diagnostic use.

II. SUMMARY OF TEST

The identification of *Treponema pallidum* antibodies aids in the diagnosis of syphilis caused by the microorganisms belonging to the genus *Treponema* and provides epidemiological information on syphilis.

Serological tests for syphilis were first used in 1906 with the development of the nontreponemal complement fixation test by Wasserman. The nontreponemal tests measure both immunoglobulin G (IgG) and M (IgM) antilipid antibodies formed by the host in response both to lipoidal material released from damaged host cells early in infection and to lipid from the treponeme itself. Because of either the lipidic nature of the antigen or some unusual property of the antibodies, the antigen-antibody reaction remains suspended, and flocculation occurs, rather than agglutination or precipitation as in most other serologic tests[1].

While useful in the diagnosis of suspected syphilis infection, nontreponemal tests are nonspecific. False positive tests may account for a significant proportion of reactive results necessitating an additional test to identify the presence of specific antibodies to *T. pallidum.*

Hemagglutination (MHATP) tests for *T. pallidum* have gained wide acceptance since their emergence in the mid 1960's[2,3,4] as a confirmatory procedure following a reactive nontreponemal assay or as a screening procedure. Automation has enhanced the value of the test by significantly reducing the amount of time and labor needed to perform the assay[5,6]. OLYMPUS PK TP SYSTEM has been developed to provide uniform reagents which are stable, easy to handle, and suitable for use on the OLYMPUS PK7200, Automated Microplate System[7,8].

The results obtained are provided to the user in a computer generated printout. All specimens which are repeatedly reactive or indeterminate with the PK TP SYSTEM are considered positive for antibodies to *T. pallidum* by the criteria of the PK TP assay. For complete details on the setup and operation of the OLYMPUS PK7200, refer to the PK7200 Operator's Manual.

III. PRINCIPLE OF PROCEDURE

The test is based on the principle of agglutination and pattern recognition. The OLYMPUS PK TP SYSTEM utilizes fixed chicken erythrocytes sensitized with components of the pathogenic *T. pallidum* (Nichols Strain).

The test sample is diluted in a sample diluent composed of phosphate-buffered saline containing normal rabbit testicular extract and cell components of sonicated Reiter *T. phagedenis*. This sample diluent minimizes nonspecific reactions. The sensitized cells are added to the test mixture and reactants are allowed to settle in a patented, terraced microplate well.

Hemagglutination occurs in the presence of *Treponema pallidum* (TP) antibodies in specimens. Visually, a reactive test is a homogenous layer of cells. A nonreactive test would result in a compact dense button surrounded by a clear zone. The PK7200 instrument will read the settling patterns of erythrocytes in each well based on the threshold settings chosen for each reagent. The PK7200 determines the presence or absence of antibodies to *T. pallidum* using a CCD (charged coupled device) camera which

captures the well image and allows differentiation of agglutinated and unagglutinated patterns.

IV. REAGENTS

OLYMPUS PK TP SYSTEM is available in a kit sufficient to perform 3000 tests:

RECONSTITUTING SOLUTION (A) – 1 bottle, 130mL. This reagent is used for reconstitution of the lyophilized SENSITIZED CELLS. The reagent contains a phosphate-buffered saline solution with 0.1% sodium azide.

SAMPLE DILUENT (B) - 5 bottles, 189mL each. The diluent consists of a phosphate-buffered saline solution containing normal rabbit testicular extract, cell components of sonicated Reiter *Treponema phagedenis*, and 0.1% sodium azide. Tartrazine (FDC No.4) [20 ppm] and Fastgreen (FDC No. 3) [2 ppm] have been added to impart a green color.

SENSITIZED CELLS (C) - 11 vials of lyophilized, fixed chicken erythrocytes. Each vial must be reconstituted with 10 mL of RECONSTITUTING SOLUTION. Reconstituted cells are stable for 5 days and should be stored at 2-8°C for maximum stability.

V. WARNINGS AND PRECAUTIONS

The OLYMPUS PK TP SYSTEM is for in vitro diagnostic use.

1) Avoid contamination of reagents or specimens with saliva, which can cause indistinguishable agglutination patterns. Do not mouth pipette any reagents.

2) The microplates must be clean before use. Improper washing of the microplates can adversely affect a test result by causing a false positive or false negative reaction. The suggested washing procedure can be found in the Standard Operating Procedure Manual for the PK7200.

3) Avoid freezing of the reconstituted SENSITIZED CELLS.

4) Sodium azide is included as a preservative. Sodium azide has been reported to form explosive lead and copper azides in laboratory plumbing. To prevent azide buildup, flush with large volumes of water if solutions containing azide are disposed of in the sink.

5) Visible signs of microbial growth or gross turbidity in the reagent may indicate degradation and warrant discontinuance of use.

6) Handle all specimens, control material and serum-based reagents as if potentially infectious. Refer to the Centers for Disease Control's guidelines on specimen handling[9].

7) Clean pipettes should be used to reconstitute all reagents. Clean glass or plastic containers should be used for reagent preparation.

8) Serum is the specimen of choice for this test. EDTA plasma is suitable for screening, however, field use has demonstrated a higher incidence of false positive results. Therefore, **serum** must be used for all repeat testing of initially reactive or indeterminate results obtained from plasma samples.

9) The performance of this assay has not been established with plasma samples employing sodium citrate or heparin as the anticoagulant.

10) The effects of specimen microbial contamination on this assay can not be predicted.

11) Carryover between specimens is a potential source of interference.

12) Positive and negative control material should be handled in the same fashion as donor samples.

13) When specimen fails to be added to the PK assay, the potential exists for a false negative result to occur.

14) Inadequate adherence to the package insert can result in erroneous results.

15) The use of calibrated or verified equipment is required.

VI. REAGENT PREPARATION

1) Reconstitute, as needed, each vial of SENSITIZED CELLS with 10 mL of RECONSTITUTING SOLUTION. Replace the stopper and gently invert to assure thorough mixing. Allow to reconstitute at room temperature (15-30°C) for a minimum of 30 minutes or overnight at 2-8°C to ensure complete rehydration.

2) Reconstituted cells are stable for 5 days and should be stored at 2-8°C for maximum stability.

3) After the reconstitution period, gently swirl (DO NOT VORTEX) the rehydrated cells to assure thorough resuspension. Follow steps under heading, "DIRECTIONS FOR USE, for use on the instruments.

4) SENSITIZED CELLS from the same lot may be pooled. The mixture is stable for five days from the earliest reconstitution date of the vials contained in the mixture.

5) SENSITIZED CELLS from one lot number should not be mixed with those of another lot number.

6) SAMPLE DILUENT from the same lot can be pooled for use on the instruments as long as good laboratory practices are followed.

7) The date of reconstitution and the reconstituted expiry should be recorded on the reagent containers.

8) The SAMPLE DILUENT and RECONSTITUTING SOLUTION are not matrixed to the SENSTIZED CELL lot.

Note: All reagents should be brought to room temperature (15-30°C) prior to use on the analyzer.

VII. STORAGE

1) Store the OLYMPUS PK TP SYSTEM test kit at 2-8°C. DO NOT FREEZE.

2) The OLYMPUS PK TP SYSTEM should not be used after the expiration date which is printed on the outside of the package.

3) Reconstituted cells are stable for five (5) days and should be stored at 2-8°C for maximum stability. DO NOT FREEZE.

4) Visible signs of microbial growth or gross turbidity in the reagents may indicate degradation and warrant discontinuance of use.

VIII. SPECIMEN COLLECTION AND PREPARATION

OLYMPUS PK TP SYSTEM may be used with serum or EDTA plasma. Serum is the preferred specimen. Specimens for repeat testing must be obtained from the same draw. The sample should be free of particulate matter. If erythrocytes or other visible components are contained in the sample, remove by centrifugation to prevent interference with the test results. The PK instruments' Standard Operating Procedures require centrifugation of samples within 10 hours of analysis and centrifugation for a minimum of 10 minutes at a minimum of 1000 x g. These requirements exist for the purpose of optimizing red cell sampling. Therefore, plasma or serum samples tested using the PK TP assay do not to comply with these requirements as long as the plasma or serum is free from particulate matter. Specimens are acceptable for testing if they do not exceed any of the following values:

Free hemoglobin	750 mg/dL
Total bilirubin	30 mg/dL

Samples which exceed these values may require alternate testing. Lipemia does not interfere with test results.

Store plasma and serum specimens at 2-8°C. ***Plasma and serum specimens may be tested for up to 5 (five) days after collection on the PK7200 analyzer.***

Sera may be stored at ≤-20°C, if testing cannot be performed within the specimen age requirements defined above. Avoid repeated freezing and thawing of specimens. Thorough mixing of frozen samples is necessary after thawing and prior to testing. Allow the specimens to come to room temperature before testing (a minimum of 10-30 minutes after thawing).

Inactivation of sample serum is not required but inactivated serum can also be used in the test. Serum may be heated for 30 minutes in a 56°C water bath without affecting the test outcome. Specimens to be heated should be at room temperature before placing in the water bath. Allow specimens to return to room temperature before testing (a minimum of 10-30 minutes after heating).

IX. MATERIALS

MATERIALS PROVIDED IN THE OLYMPUS PK TP SYSTEM:

- RECONSTITUTING SOLUTION
- SAMPLE DILUENT
- SENSITIZED CELLS

MATERIALS REQUIRED BUT NOT PROVIDED:

- OLYMPUS terraced microplates
- Pipetting devices for: 1.0 mL, 5.0 mL, and 10.0 mL
- OLYMPUS PK7200 Automated Microplate System
- OLYMPUS PK TP SYSTEM CONTROL (Catalog Number: PH3500)

X. DIRECTIONS FOR USE

The PK Instrument is a programmable instrument whose operation is controlled by software defined by the user. Validated PK TP parameters may be incorporated with routine operating files or defined in a separate file. If you are not familiar with this process, please consult the PK7200 Operator's Manual. Programming of the PK TP parameters is found in section 8 of the PK7200 Operator's Manual.

Examples of working files for the PK TP test are shown below for the PK7200. Good laboratory practice dictates that each laboratory validates the operating parameters.

RECOMMENDED PARAMETERS

Olympus has established recommended parameters for both instruments based upon application development testing with characterized samples. The final plasma/serum dilution must be in the range of 1/23 - 1/25. The following parameters will achieve this range.

RECOMMENDED VOLUMES FOR PK7200

Parameter Set	Sample	Diluted Sample	Sample Diluent	Reagent	Final Plasma/Serum Dilution
1	40 uL	15 uL	250 uL	35 uL	1/24
2	60 uL	10 uL	250 uL	35 uL	1/23

RECOMMENDED THRESHOLDS AND SETTINGS FOR THE PK7200

	P/C (r)		SPC		LIA		LIA Selection	BG/C	Temperature	
	(+) Limit	(-) Limit	Low	High	(+) Limit	(-) Limit			Setting	Instrument Range
PK7200	41	26	16	16	240	100	5	Low	28-32°C	± 3°C

EXAMPLE:

PK7200

PARAMETERS	VOL	STROKE PIN
Sample Volume	40 uL	
Diluent Volume	250 uL	G 0.25
Ratio	160 uL/1000 uL	
Diluted Sample Volume	15 uL	
Reagent Volume	35 uL	
Channel Name	SYP	
Channel Designation	(1-12)	
Decision Logic	+/-	
Temperature Setting	28-32^{o}C	
Incubation Time	60 minutes	
Well	16	
Thresholds:		
SPC	Low	16
	High	16
P/C	(+) Limit	41
	(-) Limit	26
LIA	(+) Limit	240
	(-) Limit	100
LIA Selection		5
BG/C Limit		Low

Note: Remember to save these changes on the master program disk and on the hard drive on the PK7200.

All reagents, diluents, and specimens should be at room temperature (15-30°C) prior to analysis.

PK7200 Prep Procedure for the OLYMPUS PK TP SYSTEM

To use the reagents on the analyzer:

1) Place the reconstituted SENSITIZED CELLS into the designated channel of the reagent container. Thorough, uniform mixing of SENSITIZED CELLS is important. Prior to placing on the analyzer, check reagent trough to ensure that red cells are not settling out of solution. If settling of the red cells is observed, use a pipette to carefully suspend the cells. Place the reagent container and mixing comb on the instrument. Press the MIX button on the analyzer to start the motion of the mixing comb if there is to be any delay in initiating processing.

2) Place the appropriate primary diluent line into the diluent container which is filled with SAMPLE DILUENT.

3) Remove the G stroke pins for the diluent lines only if a black rack with tubes of saline is not being processed at the beginning of the run.

4) Push the PREP button on the analyzer.

5) When the PREP cycle is complete, replace the G stroke pins, being sure to place the one marked "**G 0.25**" under the syringe that will be used to aspirate the SAMPLE DILUENT.

6) Press the DIAG button on the analyzer control panel to expel bubbles in sample and diluted sample probes.

7) Proceed with sample analysis as described in the OLYMPUS PK7200 Operator's Manual.

8) Please refer to Section XI., Quality Control, for instructions about the use of control samples.

XI. QUALITY CONTROL

The PK TP SYSTEM CONTROL SET must be tested at the beginning and end of each batch of samples assayed (maximum batch size 357 samples), after the addition of reagents, and after interruption or delays in processing. Additional QC testing may be performed by the user by including other well-characterized specimens or referenced sera.

Perform the test as described under Section X, DIRECTIONS FOR USE, using the reactive and nonreactive controls as the specimens. The reactive control should produce a positive (+) reaction and the nonreactive control should produce a negative (-) reaction with the test. If the appropriate results are not obtained with the controls, all assay results within that batch are invalid and must be retested. Repeat testing making sure that the volume of control is sufficient for adequate instrument sampling (>1.5 mL). When control material repeatedly fails to perform as expected, contact Olympus Immunohematology Technical Services at 1-800-447-5852.

XII. INTERPRETATION

The PK7200 instrument will read the settling patterns of erythrocytes in each well based on the threshold settings chosen for each reagent. See the OLYMPUS PK7200 Standard Operating Procedure Manual, Analyzer Reaction Interpretation section, for complete details of the analyzer's interpretation of reactions. The threshold limits are programmed into the PK7200 under the current operating conditions.

As soon as possible after analyzer interpretation, results should be verified by visual judgment of the reaction pattern against the photometric data. All photometer results should be visually reviewed. Visually, a reactive test is a homogeneous layer of cells. A nonreactive test would result in a compact dense button surrounded by a clear zone. Additional testing must be performed on any sample for which visual and analyzer interpretations do not agree. Refer to the Analyzer Reaction Interpretation section of the analyzer's SOP Manual.

PK7200

The presence or absence of antibodies to *Treponema pallidum* is determined by the PK7200 by a CCD camera which analyzes the well images and differentiates agglutinated and non-agglutinated patterns. The PK7200 employs three assessment parameters for each microplate well containing OLYMPUS PK TP SYSTEM reagents and test specimens:

- SPC Sharpness of the edge of the cell button
- LIA Quantity of cells in the center of the well
- P/C Ratio of the average light transmittance of the peripheral and central values

The parameters, SPC, LIA and P/C, are compared to programmable thresholds to obtain an interpretation (+, -, ?) for each reaction.

The most important parameter resulting from the image analysis system is SPC. If the SPC is determined positive, then either a positive or indeterminate LIA or P/C value will result in an overall positive results interpretation for the reaction. A positive SPC value together with a negative value for either the LIA or P/C will cause the channel result to be an indeterminate result. If the SPC is determined negative, then either a negative or indeterminate LIA or P/C value will result in an overall negative result interpretation for the reaction. A negative SPC value together with a positive value for either the LIA or P/C will cause the channel result to be an indeterminate result. Please refer to Table 1 for further clarification.

TABLE 1: DECISION LOGIC FOR PK7200 RESULTS INTERPRETATION

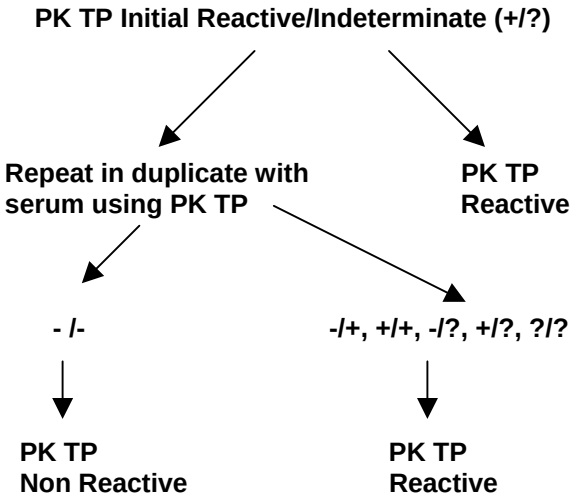
Channel Results Interpretation	SPC	LIA	P/C
Positive	+	+ or ?	+ or ?
Negative	-	- or ?	- or ?
Indeterminate	+	-	-
	+	-	+
	+	+	-
	-	+	+
	-	+	-
	-	-	+
	?	+,-, or ?	+, -, or ?

XIII. INTERPRETATION OF RESULTS (Table 2)

A sample reported as nonreactive on initial screening is considered nonreactive for antibodies to *T. pallidum* and needs no further testing.

An EDTA plasma sample which is reactive or indeterminate (?) on initial screening with the PK TP SYSTEM, is considered initially reactive by the PK TP SYSTEM, but prior to interpretation, the test may be repeated in duplicate using a serum specimen from the same draw. If serum is the initial sample tested, retesting in duplicate on serum is optional. The duplicate tests must occur in the same run. If either duplicate is reactive or indeterminate, the specimen is to be interpreted as repeatedly reactive for antibodies to *T. pallidum* by the criteria of the PK TP SYSTEM. Initially reactive plasma or serum specimens which are negative in both of the duplicate re-tests are considered negative by the criteria of the PK TP SYSTEM.

TABLE 2: INTERPRETATION OF RESULTS FOR PK™ TP



XIV. EXPECTED VALUES

A sample reported as reactive on the OLYMPUS PK TP SYSTEM is considered to be reactive for IgG and/or IgM antibodies to *T. pallidum* by the criteria of the PK TP System. Reactive results may indicate active, past, or successfully treated syphilis infections. The diagnosis of syphilis depends not only on the laboratory findings, but also on a carefully obtained history and a thorough physical examination.

Studies performed on 3,440 random blood donors have shown the initial plasma reactive rate to be 1.48% (51/3440) and the repeat reactive rate to be 0.47% (16/3432) when samples were tested on the PK TP System on the PK7200. When tested against samples from individuals at varying stages of the disease (primary, secondary and tertiary), the overall reactive rate was 93.9% (447/476) by the PK TP System. By comparison, RPR positively identified 88.2% (420/476) of the samples. FTA-ABS testing showed 94.1% of the population (444/472) to be reactive.

One hundred percent (100%) of samples tested from both treated and untreated patients in both the primary and secondary stages of the disease were detected by the PK TP System. Samples from both treated and untreated tertiary or latent stage patients were also tested with the PK TP System. Ninety-two percent (92%) of the samples were positively identified.

Of samples from individuals with unknown disease status, 77% were identified by the PK TP System as compared to 69.9% by RPR.

Samples from individuals with autoimmune disease, Lyme disease, Legionella, infectious mononucleosis and Rubella, including drug addicts and multiparous women, have shown the reactive rate to be 4.37% (10/229) when the PK TP System was employed. Eight of these ten samples reactive with PK TP were also reactive by either RPR and/or FTA-ABS.

Some institutions may encounter a higher rate of false positive results with apheresis donors. These results seem to be related to the mechanism of sample collection and preparation for some apheresis donors. OLYMPUS' experience with this situation reveals that the serum repeat algorithm minimizes this false positive situation. An alternative screening method may be preferred.

XV. LIMITATIONS OF THE PROCEDURE

OLYMPUS PK TP SYSTEM has been shown to be safe and effective for the large scale detection of antibodies to *Treponema pallidum* in serum or EDTA plasma from blood donors when used in accordance with the instructions provided with the kit. Serum must be used for any repeat testing on initially reactive or indeterminate results obtained from plasma samples.

As with all serological tests for syphilis, interpretation of results obtained with the OLYMPUS PK TP SYSTEM must take into consideration the donor's history and other clinical and/or laboratory findings.

This product is for use only in screening blood donors and has not been evaluated as a serologic test for syphilis outside the blood bank setting. The product cannot be considered a standard test for syphilis in other test settings. The OLYMPUS PK TP SYSTEM may not be used to monitor the efficacy of therapy or reinfection.

XVI. SPECIFIC PERFORMANCE CHARACTERISTICS

Clinical Sensitivity: (Tables 3 & 4)

The OLYMPUS PK TP SYSTEM and RPR methods were compared by testing 328 samples from syphilitic individuals who had been previously characterized as primary, secondary, tertiary, both treated and untreated. In a second study, 147 known FTA-ABS reactive specimens were tested by the OLYMPUS PK TP SYSTEM and RPR methods. The results of both studies are summarized in Tables 3 & 4.

TABLE 3: CLINICAL SENSITIVITY of PK TP[a] , RPR and FTA-ABS

SYPHILIS CATEGORY	NUMBER =	NUMBER REACTIVE		
		PK TP	RPR	FTA-ABS
PRIMARY				
Untreated	55	55	55	55
Treated	40	40	39	40
Unknown	50[b]	25	25	24
SECONDARY				
Untreated	51	51	46	49[c]
Treated	44	44	40	42[c]
Unknown	3	3	3	3
TERTIARY OR LATENT				
Untreated	23	21	20	22
Treated	2	2	2	2
Unknown	60	59	51	60
UNCHARACTERIZED	148	147	139	147
TOTAL	476	447	420	444
CLINICAL SENSITIVITY		93.9%	88.2%	94.1%

PK TP REACTIVE includes REACTIVE and INDETERMINATE results.

[a] PK TP testing performed on the PK7100 instrument.
[b] Twenty-four specimens were diagnosed by the presence of chancre only.
[c] Two samples not tested for FTA-ABS

TABLE 4: SENSITIVITY OF PK TP SYSTEM ACCORDING TO DISEASE AND TREATMENT STAGE

	n[a]	NUMBER REACTIVE		SENSITIVITY	
		PK TP SYSTEM	RPR	PK TP SYSTEM	RPR
Primary	145	120	119	82.8%	82.1%
Secondary	98	98	89	100.0%	90.8%
Tertiary or Latent	85	82	73	96.5%	85.9%
Untreated	129	127	121	98.5%	93.8%
Treated	86	86	81	100.0%	94.2%
Unknown	113	87	79	77.0%	69.9%

PK TP REACTIVE includes REACTIVE and INDETERMINATE results.
[a]n = all samples classified as reactive by clinical and serological findings.

Clinical Specificity: (Table 5)
OLYMPUS PK TP SYSTEM and the RPR methods were used to test specimens from the following categories: Rheumatoid factor positive, Rubella positive, Lupus Erythematosus and/or ANA positive, post HBV vaccination specimens, multiparous women, drug addicts, Lyme disease, collagen diseases, abnormal immunoglobulins, and others.

TABLE 5: CLINICAL SPECIFICITY*

Sample Category	n=	PK TP (R)		PK TP (N)	
		RPR (R)	RPR (N)	RPR (R)	RPR (N)
ANA (+) anti-DNA (+)	72	1[a]	3[b]	3[c]	65
RF (+)	34			2	32
Drug Addicts	21	2[d]			19
Collagen Disease	23				23
Lyme Disease	15	3[d]			12
Legionella	5				5
Mononucleosis (+)	11				11
Abnormal Immunoglobulins	10				10
Post HBV Vaccines	31	1			30
Multiparous Women	6				6
Rubella	1				1
TOTAL	229	7	3	5	214

* Testing performed on PK7100
R REACTIVE & INDETERMINATE
N NONREACTIVE
a FTA-ABS NONREACTIVE
b One sample was FTA-ABS reactive, two samples were FTA-ABS nonreactive.
c Two samples were FTA-ABS nonreactive, one was not tested.
d FTA-ABSreactive.

Random Blood Donors

PK7200 (Tables 6 & 7)

Random blood donor specimens (3,440) were tested using the OLYMPUS PK TP SYSTEM on the PK7200 instrument at two major blood centers in comparison with their test of record for screening blood donors for antibodies to *T. Pallidum* (OLYMPUS PK TP SYSTEM on the PK7100 instrument). Donors who tested initially reactive with plasma samples were tested in duplicate with serum samples. Repeat reactive samples from testing on either instrument were confirmed with either the FTA or MHATP test. An additional twenty-four known reactive samples gave positive results when tested with the PK TP System on the PK7200.

TABLE 6: OLYMPUS PK TP SYSTEM RANDOM DONOR RESULTS: PK7200 & PK7100 INITIAL, SERUM REPEAT AND CONFIRMATORY TESTING

PK TP SYSTEM		NUMBER		FTA/MHATP	
PK7200	**PK7100**	**INITIAL (PLASMA)**	**REPEAT***	**R**	**N**
N	N	3339	3415		
N	R	50	1	0	1
R	N	24	7	2	5
R	R	27	9	6	3
TOTAL		3440	3432[a]	8	9
PK7200 REACTIVE RATE		1.48%	0.47%	0.23%	
PK7100 REACTIVE RATE		2.24%	0.29%	0.17%	

R REACTIVE & INDETERMINATE

N NONREACTIVE

[a] Eight (8) samples could not be retested on the PK7200 and were removed from the analysis. Four (4) were initially reactive on the PK7100 and PK7200. All were nonreactive in duplicate when repeated with serum on the PK7100. They were not retested on the PK7200. Four (4) were nonreactive on the PK7100, initially reactive on the PK7200 but could not be repeated on the PK7200 due to mechanical problems. The samples were not retained for further testing. All four (4) samples occurred on the same day of testing.

* Following serum repeat testing of initial plasma reactives.

TABLE 7: RESULTS OF PK7200 REPEAT TESTING WITH SERUM SAMPLES AND CONFIRMATORY TESTING OF RANDOM DONORS

PK7200 (REPEAT TESTING ON SERUM)	PK7100		REACTIVES AND DISCORDANTS RECONCILED BY FTA-ABS OR MHATP	
	R	N	R	N
REACTIVE	9	7	8	8
NONREACTIVE	1	3415	0	3416
% CONCORDANCE	3424/3432 = 99.8%		3424/3432 = 99.8%	
RELATIVE SENSITIVITY	9/10 = 90.0%[a]		8/8 = 100%	
RELATIVE SPECIFICITY	3415/3422 = 99.8%[b]		3416/3424 = 99.8%[c]	

R REACTIVE & INDETERMINATE
N NONREACTIVE
[a] 95% Confidence interval is 0.555-0.97
[b] 95% Confidence interval is 0.992-0.998
[c] 95% Confidence interval is 0.992-0.998

Reproducibility:

PK7200 (Table 8)
The reproducibility of the OLYMPUS PK TP SYSTEM on the PK7200 was evaluated at two blood centers. One center tested 100 nonreactive random donor EDTA specimens and 11 confirmed reactive samples on each of three days. The other center tested 140 nonreactive random donor EDTA specimens and 12 confirmed reactive samples on each of three days. Results are summarized in Table 10.

TABLE 8: REPRODUCIBILITY OF THE OLYMPUS PK TP SYSTEM ON THE PK7200

	N=	CORRELATION			
		DAY 1	DAY 2	DAY 3	TOTAL
REACTIVE	23	100%	100%	100%	100%
NONREACTIVE	240	99.6%	97.5%	97.5%	98.2%
COMBINED REACTIVE & NONREACTIVE	263	99.6%	97.7%	97.7%	98.4%

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Manufactured by:
FUJIREBIO INC.
Tokyo, Japan

Manufactured for:
OLYMPUS
Melville, NY 11747

Customer Service: 800-223-0125
Technical Support: 800-447-5852

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